AWARD NUMBER: W81XWH-14-1-0188

TITLE: Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments

PRINCIPAL INVESTIGATOR: Glenn K. Klute, PhD

CONTRACTING ORGANIZATION:
Seattle Institute for Biomedical and Clinical Research
Seattle, WA 98108

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PREPARED FOR:
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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**14. ABSTRACT**

The objective of this project is to provide active lower limb amputees who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The specific aims are to: (1) Identify the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration.

During the current reporting period, we have enrolled 5 lower limb amputees into an IRB-approved protocol to walk on a treadmill for up to 30-minutes in a chamber at 20, 30, and 35 degrees Celsius at 50% relative humidity. The cross-over experimental design randomizes the order of the study prostheses. Two subjects have completed the entire protocol. Subject recruitment is on-going.

**15. SUBJECT TERMS**

Lower extremity amputee, transtibial, artificial limb, prosthesis, skin temperature, perspiration

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## 1. Introduction

Lower limb amputees often complain about uncomfortable residual limb skin temperatures and the accumulation of perspiration inside their prostheses that sometimes leads to an insecure prosthetic suspension (i.e., the prosthesis falls off during vigorous activity). The purpose of this project is to provide active lower limb amputees who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The scope of this research includes: (1) identifying the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) comparing the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration. The work to achieve these aims includes: (1) fabricating, assembling, and fitting standard-of-care and dynamic air exchange prostheses to volunteer lower limb amputees, and (2) conducting a human subject experiment with subjects walking on a treadmill in at different environment temperatures. The dynamic air exchange prosthesis is expected to significantly surpass the thresholds at which the standard-of-care fails.

## 2. Keywords

Lower extremity amputee, transtibial, artificial limb, prosthesis, skin temperature, perspiration

## 3. Accomplishments

### What were the major goals of the project?

The statement of work (SOW) for this project includes two major tasks:

Major Task 1. Fabricate dynamic air exchange prosthetic components at the Arusha Control site. Activities associated with this task include: purchasing supplies, receiving residual limb casts from the VA Puget Sound Health Care System (VAPSHCS) site, fabricating custom, moisture-wicking textile sock with a proximal elastomeric seal, fabricating prosthetic sockets, fabricating electronic components, fabricating housings, performing bench and quality assurance testing, and shipping components to the VAPSHCS site.

The approved SOW for this task identified four milestones and corresponding target dates shown in Table 1.

**Table 1**: Major task 1 milestones.

| Major Task 1 Milestones | Target Timeline (months) | Actual Timeline (months) |
|---|---|---|
| Milestone 1.1: Deliver unit (1) | 3 | 7 |
| Milestone 1.2: Deliver units (4) | 6 | 10 |
| Milestone 1.3: Deliver units (4) | 9 | TBD |
| Milestone 1.4: Deliver units (4) | 12 | TBD |

TBD: to be done.

Major Task 2. Conduct a human subject experiment at the VAPSHCS site to compare the performance of the study prostheses. A human subject experiment with transtibial amputees (n=25) will be conducted involving two study prostheses (standard-of-care v. dynamic air exchange) and their performance in three environmental conditions (20, 30, and 35 °C and 50% relative humidity). Subjects will walk on a treadmill in an environmental

chamber and the time until loss of prosthetic suspension and the amount of perspiration accumulated/expelled will be measured. Hypotheses comparing the performance of the two study prostheses will be tested, the results documented and disseminated to program officials, clinicians, and amputees.

The components of the innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration will be fabricated at the Arusha Control site. Final assembly of prosthetic components and fitting of the prosthetic assemblies will occur at the VAPSHCS site.

Activities associated with this task include: obtaining and maintaining regulatory approvals, recruiting subjects, casting residual limbs, shipping casts to the Arusha Control site, receiving components from the Arusha Controls site, assembling final prostheses, conducting human subject tests, securing test data, analyzing test data, performing hypothesis tests, and documenting results.

The approved SOW for this task identified four subtasks and four milestones, with corresponding target dates, which are shown in Table 2.

**Table 2**: Major task 2 milestones.

| Major Task 2 Milestones | Target Timeline (months) | Actual Timeline (months) |
|---|---|---|
| Subtask 2.1: Obtain approval from all governing Institutional Review Boards (HRPO/IRB) | 1-3 | 3 |
| Subtask 2.2: Commission climate chamber | 1-2 | 4 |
| Subtask 2.3: Conduct human subject experiment | 3-21 | ongoing |
| Milestone 2.1: Recruit subject (1) | 3 | 7 |
| Milestone 2.2: Recruit subjects (4) | 6 | 10 |
| Milestone 2.3: Recruit subjects (4) | 9 | TBD |
| Subtask 2.4: Analyze preliminary data & report results | 9-12 | TBD |
| Milestone 2.4: Recruit subjects (4) | 12 | TBD |

TBD: to be done.

**What was accomplished under these goals?**

Major Task 1. The work of this reporting period included fabricating components to be used in assembling the study prostheses for our human subject experiments. We have fabricated components for five complete prostheses (see Figure 1) and delivered them to the VA site for human subject testing. We have fabricated additional components (see Figures 2 and 3) which are ready to be assembled as needed. These components include: the proximal port snap housings, molded pump housings, distal liner pin with wrench flats for ease of installation, electronic circuit boards, on-board control switch assemblies, 9 volt battery holder, vacuum manifolds, hose barb O-ring installations, custom socks, and system packaging using a strapped on fabric harness. We have also created prosthetist fitting aids and instructions including charts to assist with liner and sock sizing and trim lines.

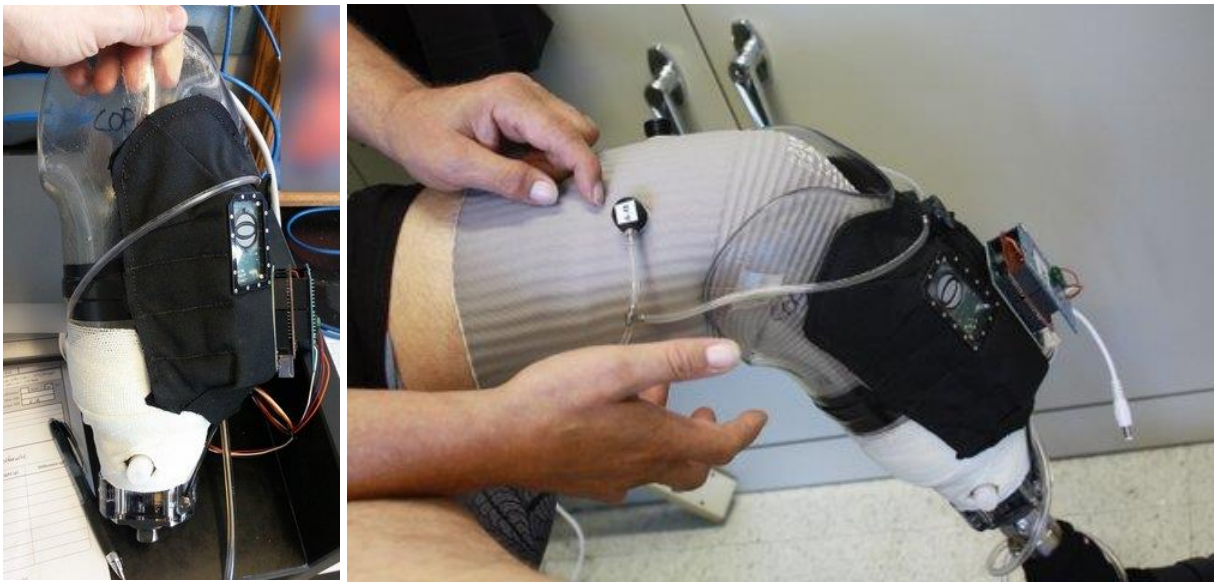
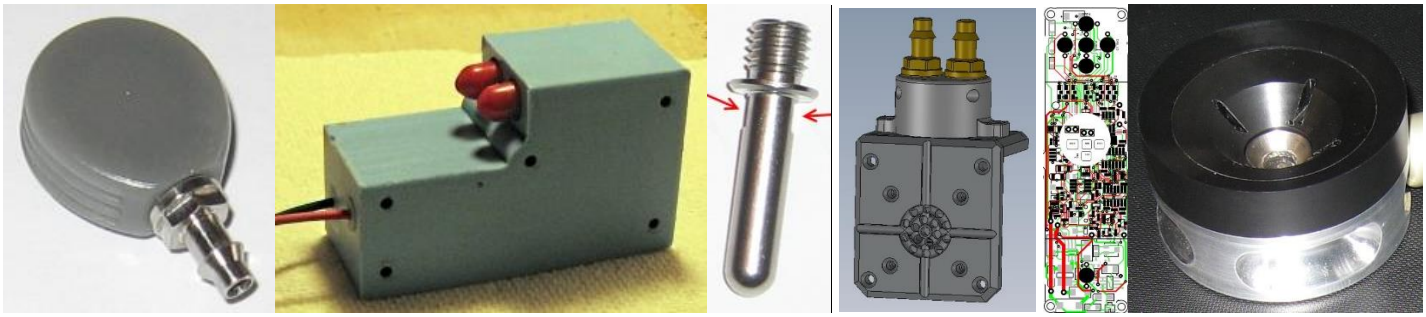
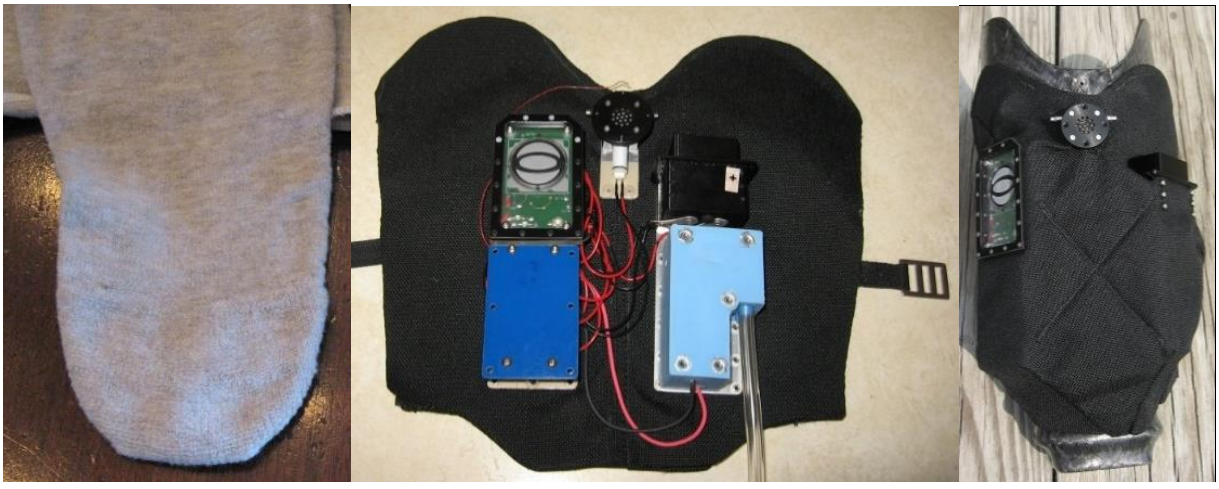


**Figure 1**: (a) An assembled dynamic air exchange prosthesis for use in human subject testing. (b) Test subject donning the dynamic air exchange prosthesis.



(a) (b) (c) (d) (e) (f)

**Figure 2**: Prosthesis components: (a) proximal port snap housing, (b) molded pump housing, (c) distal liner pin with wrench flats (see red arrows) for ease of installation, (d) vacuum manifold, (e) electronic control board and (f) lock housing.



(a) (b) (c)

**Figure 3**: Prosthesis components: (a) custom sock, (b) system packaging (interior), and (c) system packaging wrapped around a prosthetic socket (control switch, proximal manifold, and battery port visible).

Major Task 2. During the current reporting period, we performed work on the four subtasks of major task 2.

*Subtask 2.1:* Obtain (and maintain) approval from all governing Institutional Review Boards. Human subject approvals from all engaged institutions were obtained and remained continuous during the reporting period.

Documents for protocol A-18175 was reviewed by the US Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections, Human Research Protection Office (HRPO) and found to be in compliance with Federal, Dept. of Defense, and US Army human subjects protection requirements. Approval was granted to enroll up to 40 subjects for a target of 25 subjects to complete the study on 10Dec2014. Continuation documents were reviewed by HRPO on 19 June 2015 and found continuing compliance with all regulatory requirements.

The VA Institutional Review Board (IRB) reviewed and approved the initial review questionnaire (IRQ) for this protocol (00695) on 25 June 2014. The continuation of this protocol was reviewed and approved on 14 May 2015 with an expiration date of 13 May 2016. Approval was granted to enroll no more than 40 subjects in this moderate risk study.

*Subtask 2.2:* Commission climate chamber. The climate chamber was commissioned during the reporting period.

During the current reporting period, we completed construction and performed commissioning tests on the climate controlled chamber (see Figure 4) within which to conduct our planned human subject experiments. From ambient conditions (20 °C and 38% relative humidity), it takes less than two hours to reach our most extreme test conditions (35°C and 68% relative humidity).

(a) (b)

**Figure 4**: (a) Climate chamber with treadmill, (b) red zipper entry and exit port, and (c) front view of a lower-limb amputee wearing the dynamic air exchange prosthesis while walking on the treadmill in the climate chamber.

*Subtask 2.3:* Conduct human subject experiments. Human subject experiments have been conducted during the reporting period and are continuing.

On June 18, 2015, we successfully completed the first study visit involving a lower limb amputee wearing the dynamic air exchange prosthesis in our climate chamber at 35 °C and 50% relative humidity (see Figure 5). Data collected included skin temperatures and amount of accumulated and expelled perspiration. Five subjects have been enrolled (see Table 3) and experiments are in progress.

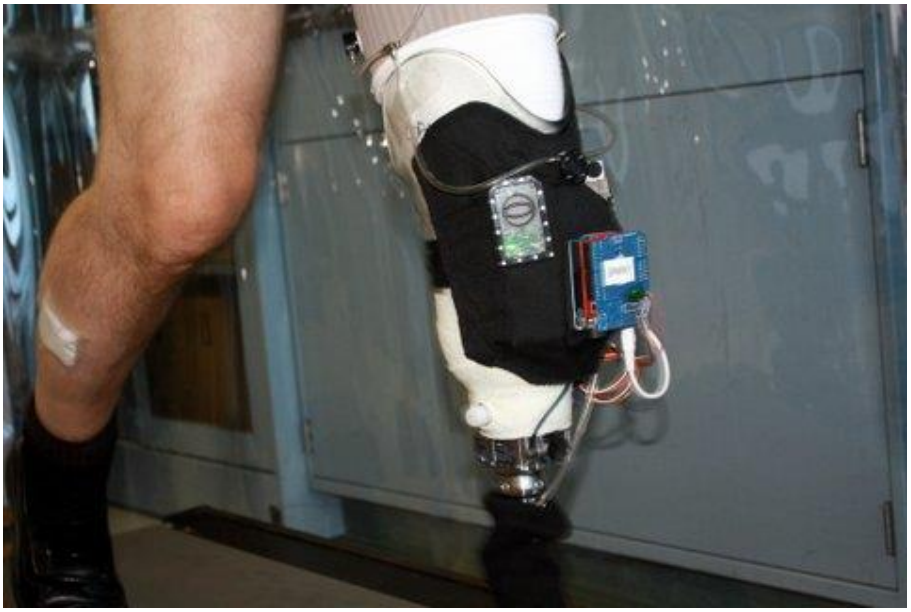


**Figure 5**: Lower-limb amputee wearing the dynamic air exchange prosthesis while walking on the treadmill in the climate chamber.

**Table 3:** Human subject quarterly enrollment targets over the two-year grant period. All human subject procedures will be performed at site 1. Actual enrollment data is provided for the current reporting period (Year One).

| **Transtibial Amputees** | **Year One** | | | | **Year Two** | | | | **Total** |
|---|---|---|---|---|---|---|---|---|---|
| | **Q1** | **Q2** | **Q3** | **Q4** | **Q5** | **Q6** | **Q7** | **Q8** | |
| Actual / Target Enrollment (per quarter) | 0/1 | 0/4 | 3/4 | 2/4 | /4 | /4 | /4 | /0 | /25 |
| Actual / Target Enrollment (cumulative) | 0/1 | 0/5 | 3/9 | 5/13 | /17 | /21 | /25 | /25 | /25 |

We are currently expanding our human subject recruitment efforts to increase enrollment. Please see Section 5. Changes/Problems of this report for details.

*Subtask 2.4:* Analyze preliminary data & report results. Experimental data was collected during the current reporting period and is ongoing.

Two subjects have completed all study procedures (six study visits each involving treadmill walking in the environmental chamber). Neither subject (COPA 01 and COPA 02) lost adherence during the 30-minute treadmill walk wearing the dynamic air exchange (DAE) or standard-of-care (SoC) prostheses with the chamber at 20 °C, 30 °C, and 40 °C with 50% relative humidity. Increasing chamber temperature resulted in greater perspiration as expected (see Table 4). Subjects appear to sweat more while wearing the DAE prosthesis than the SoC prosthesis.

**Table 4:** Total sweat measured from two participants who have completed all study procedures.

| | COPA 01 | | | | | | COPA 02 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DAE | | | SoC | | | DAE | | | SoC | | |
| | 20°C | 30°C | 35°C | 20°C | 30°C | 35°C | 20°C | 30°C | 35°C | 20°C | 30°C | 35°C |
| Total Sweat (g) | 0.61 | 6.18 | 15.40 | 0.40 | 1.14 | 5.69 | 2.53 | 4.65 | 9.64 | 0.09 | 1.62 | 1.47 |

DAE: dynamic air exchange
SoC: standard-of-care

This subtask includes a statistical analysis to aid in determining the number of subjects required to accurately test the study hypotheses. This task remains incomplete until additional subjects have completed all study procedures.

**What opportunities for training and professional development has the project provided?**

Nothing to report.

**How were the results disseminated to communities of interest?**

Nothing to report.

**What do you plan to do during the next reporting period to accomplish the goals?**

During the next year, we plan to continue fabricating prosthesis components, assemble complete prostheses, enroll lower limb amputee participants, and conduct human subject tests using our approved protocol. Our most significant challenge is human subject recruitment, for which we have expanded our recruitment plan (please see Section 5. Problems/Changes for details).

## 4. Impact

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

Nothing to report.

## 5. Changes/Problems

There have been no significant changes in the project or its direction.

**Actual or anticipated problems or delays and actions or plans to resolve them**

We have developed plans to improve human subject recruitment and access to prosthetic services for FY16.

Human subject recruitment: We began the reporting period recruiting human subjects for this specific study (#00695) by posting flyers at IRB-approved kiosks and screening VAPSHCS clinical lists and the VA Computerized Patient Record System (CPRS) for appropriate candidates. Appropriate candidates are sent approach letters and contacted by telephone. We also used contact information from the PI's IRB-approved Subject Registry (#00433). Recruitment has not been as fast as we would like, so we are bolstering our recruitment efforts. Instead of requesting IRB-approval for additional, advertising schemes with details of this study (00695), we are employing an indirect recruitment scheme. In the spring, we sought and received IRB-approval to use mass media advertising and contact with potential subjects through VA Community Based Outpatient Clinics (CBOCs) for another of the PI's IRB-approved human subject studies (i.e., #00649 Social activity networks and the mobility of lower-limb amputees). This study (00649) is significantly less demanding as it involves simply wearing a Fitbit activity monitor for up to two years. We are also seeking approval to post flyers and recruit at private practice prosthetic clinics in the greater metropolitan area for the Fitbit study (00649). At the time of consent (00649), we also ask the subjects to provide consent to be placed in our Subject Registry (00433). Once in the Subject Registry, we can then immediately contact them for potential participation in this study (00695). We expect improved recruitment in FY16.

Prosthetic services: During the reporting period, we budgeted for a research prosthetist to order prosthetic supplies, assemble prosthetic systems, fit prostheses to test subjects, perform adjustments and alignments, participate in research team meetings to discuss findings, assist in formulating study conclusions, and assist in result documentation. The individual we intended for this role, Mr. Kevin Clark, L/CPO became unavailable after the award date. With the occasional assistance of a VA prosthetist, Mr. Wayne Biggs, L/CPO, we leveraged VAPSHCS prosthetic services for these tasks while we sought a permanent solution. The lack of a dedicated research prosthetist made the fabrication and fitting of study prostheses challenging to schedule. In August 2015, we hired a VA-funded research prosthetist, Mr. Daniel Daley, to fulfil this role. We anticipate no further delays related to the delivery of prosthetic services.

**Changes that had a significant impact on expenditures**

Nothing to report.

## 6. Products

We anticipate reporting a number of projects for the work in year two of this project.

**Publications, conference papers, and presentations**

Nothing to report.

**Journal publications**

Nothing to report.

**Books or other non-periodical, one-time publications.**

Nothing to report.

**Other publications, conference papers, and presentations.**

Presentation: Dr. Klute presented a briefing on this project to Congressman Adam Smith at the Harborview Medical Center on 4Aug2014.

Presentation: Dr. Klute presented an interim report on this project to Mr. Hughes Turner, Deputy Chief of Staff to Secretary of the VA, during a visit to the VAPSHCS on 25March2015.

Presentation: Dr. Klute presented an interim report on this project to Admiral Ruth during a site visit to the VAPSHCS on 9Sept2015. Department of the Navy personnel in attendance included:

RDML Jeff Ruth, Commander of Navy Region Northwest
LCDR Matt Bayer, flag aide
CMC Todd Gruchalla, Command Master Chief of Navy Region Northwest
RPC Marco Mirador, Religious Programs Chief Petty Officer

**Website(s) or other Internet site(s)**

Nothing to report.

**Technologies or techniques**

Nothing to report.

**Inventions, patent applications, and/or licenses**

Nothing to report.

**Other Products**

Nothing to report.

## 7. Participants & Other Collaborating Organizations

**What individuals have worked on the project?**

| | |
|---|---|
| Name: | *Glenn K. Klute, PhD* |
| Project Role: | *PI* |

| | |
|---|---|
| Researcher Identifier (e.g. ORCID ID): | *GKLUTE* |
| Nearest person month worked: | *1* |
| Contribution to Project: | *No changes.* |
| Funding Support: | *VA Research Career Scientist (A9248-S)*<br>*Dept. of Veterans Affairs, Rehabilitation R&D Service*<br>*This award supports Dr. Klute's research (salary only) to improve the quality of life and functional status of Veteran lower limb amputees.* |

| | |
|---|---|
| Name: | *Charles King, CPO* |
| Project Role: | *Investigator* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *3* |
| Contribution to Project: | *No changes.* |
| Funding Support: | *None to report.* |

| | |
|---|---|
| Name: | *Jocelyn S. Berge, MSE* |
| Project Role: | *Investigator* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *12* |
| Contribution to Project: | *No changes.* |
| Funding Support: | *None to report.* |

| | |
|---|---|
| Name: | *Jonathan Schreven, BS* |
| Project Role: | *Research engineer / prosthetist assistant* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *12* |
| Contribution to Project: | *No changes.* |
| Funding Support: | *None to report.* |

| | |
|---|---|
| Name: | *Daniel M. Daley* |
| Project Role: | *Research prosthetist* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *2* |
| Contribution to Project: | *Prosthesis final assembly, fit, and alignment.* |
| Funding Support: | *Center of Excellence for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service* |

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

The PI has been awarded three investigator initiated grants during the current reporting period. There has been no change in the PI's level of effort and there is no overlap with the project described in this report. The three grants awarded during the current reporting period are:

Social Activity Networks and the Mobility of Lower Limb Amputees
Dept. of Veterans Affairs, Rehabilitation R&D Service 10/2014 - 9/2016
I21 RX001603 $199k
PI: Glenn K. Klute, PhD
Aims: This research has two specific aims: (1) determine if lower limb amputees are willing to use smart activity monitors as part of their daily life, and (2) discover if feedback of activity levels with or without the use of social networks (peer group activity levels and community forums) can elevate activity levels and maintain it over a prolonged period of time.

User-Controlled Variable Stiffness Prosthesis to Improve Amputee Balance
Dept. of Veterans Affairs, Rehabilitation R&D Service 6/2015 - 5/2018
I01 RX001840 $825k

PIs: Glenn K. Klute, PhD and Richard R. Neptune, PhD

Aims: This research has three specific aims: (1) To identify terrain-dependent coronal ankle properties that maximize balance recovery, (2) To identify user motor intentions before a step on uneven terrain, and (3) Determine if a novel prosthesis optimized for balance recovery and controlled by user motor intentions can improve the recovery from a step on uneven terrain when compared to the amputee's as-prescribed prosthesis.

Torsional stiffness and user preference: lower limb amputee lab test

Dept. of Veterans Affairs, Rehabilitation R&D Service 10/2015 - 9/2017
I21 RX001933 $199k
PI: Glenn K. Klute, PhD

Aims: With the help of Veteran lower limb amputees (n=15) wearing a novel prosthetic limb, this project aims to determine: (1) the preferred transverse plane stiffness and (2) the transverse plane stiffness that minimizes the transverse plane moment applied to the residual limb.

The PI had one grant end during the current reporting period. There was no change in the PI's level of effort. The research that ended included a third aim to test a novel prosthesis of similar design to the one used in the project described in this report. Importantly, the conditions under which it was tested included lower limb amputees walking on a treadmill in ambient conditions (20 °C, ~35% relative humidity) while wearing thermally-insulative garments. These human subject test conditions were significantly different than the test conditions of the project described in this report. There was no overlap with the project described in this report.

Skin Temperature Perception and Prosthetic Thermoregulation

Dept. of Veterans Affairs, Rehabilitation R&D Service 7/2012 - 6/2015
I01 RX000901-01 (A9186R) $825k
PI: Glenn K. Klute, PhD

Aims: The aims of this research include measuring thermal perception and vasomotor response to thermal stimuli, developing a novel prosthesis with the aid of a unique thermal manikin to simulate the residual limb, and conducting human subject tests to see if the dynamic air exchange induced by this prosthesis can provide thermal relief and expel accumulated sweat.

**What other organizations were involved as partners?**

Nothing to report.

## 8. Special Reporting Requirements

Please see Department of Defense Quad Chart in Appendix B.

## 9. Appendices

This annual report includes two appendices:

A. Human subjects enrollment table.
B. Department of Defense Quad Chart (updated October 28, 2015).

**Appendix A: Human Subjects Enrollment Table**

Protocol: A-18175
Title: Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments

Continuation documents for protocol A-18175 was reviewed by the US Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections, Human Research Protection Office (HRPO) on 19 June 2015 and found to be in compliance with Federal, Dept. of Defense, and US Army human subjects protection requirements. The study is currently approved to enroll 40 subjects.

The VA Institutional Review Board (IRB) approved continuation of this protocol (VA #00695) on 14 May 2015. Approval to enroll no more than 40 subjects in this moderate risk study will expire on 13 May 2016.

**Table A**: Human subject enrollment (actual and target) over the two year grant period. Actual enrollment includes participants since the beginning of the project (September 30, 2014) through the end of year one (September 29, 2015). All human subject procedures are performed at site 1.

| **Patient Population** | **Year One Actual/Target** | **Year Two Actual/Target** |
|---|---|---|
| Transtibial Amputees | 5 / 13 | TBD / 25 |

**Appendix B: Department of Defense Quad Chart (updated 28 October 2015)**

# Perspiration Thresholds & Secure Suspension for Lower Limb Amputees in Demanding Environments

Log Number OR130260, Award Number W81XWH-14-1-0188

**PI:** Glenn K. Klute, PhD **Org:** Seattle Institute for Biomedical and Clinical Research **Award Amount:** $674,942

## Objective

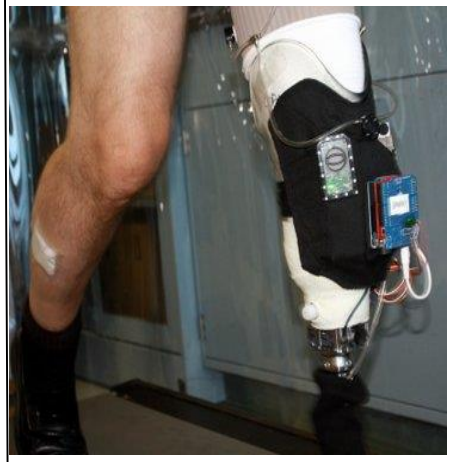
Provide active lower limb amputees who work in demanding environments with a prosthesis that remains secure despite profuse perspiration.

## Study Aims

- Identify environment & perspiration thresholds at which the current standard-of-care prosthesis fails to provide secure suspension.
- Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that expels perspiration.

## Approach

Conduct within-subject experiment with transtibial amputees (n=25) walking on a treadmill in three environmental conditions (20, 30, and 35 °C and 50% relative humidity) wearing standard-of-care and innovative prostheses.



## Innovative Prosthesis Design

A battery-powered pump creates a small pressure differential (vacuum) between the proximal and distal regions of the donned prosthesis. This pressure differential, when carefully controlled, causes air flow inside the prosthesis, providing a means for expelling perspiration into an exterior chamber while maintaining a secure suspension.

## Timeline and Cost

| Activities FY | 15 | 16 |
|---|---|---|
| IRB approvals and commission climate chamber | | |
| Recruit participants | | |
| Fabricate prosthetic components | | |
| Conduct human subject tests | | |
| Analyze & report results | | |
| **Estimated Budget ($K)** | **$342** | **$333** |

**Updated:** 28 October 2015

## FY15 Activities

- ☑ Obtain & maintain HRPO/IRB approvals
- ☑ Fabricate prosthetic components
- ☑ Enroll lower limb amputee participants (n=5 to date)
- ☑ Conduct human subject experiments
- ☐ Perform preliminary analysis & report results

## FY16 Goals & Activities

- ☐ Obtain and maintain regulatory approvals
- ☐ Fabricate prostheses
- ☐ Conduct human subject experiments
- ☐ Perform analysis & report results

## Budget Expenditure to Date

FY15 Projected Expenditure: $341,717

FY15 Estimated Expenditure: ($235,988)